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Bionpharma Inc.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:21-cv-10656
	)	
CORERX, INC.,	)	**PUBLIC REDACTED VERSION**
	)	
Defendant.	)	
	)	

DECLARATION OF MARISA MARINELLI, ESQ. IN SUPPORT OF PLAINTIFF BIONPHARMA'S APPLICATION FOR ORDER TO SHOW CAUSE WITH TEMPORARY RESTRAINTS, AND MOTION FOR PRELIMINARY INJUNCTION

Marisa Marinelli, an attorney duly admitted in the State of New York, hereby declares under penalty of perjury as follows:

1. I am a member of the firm of Holland & Knight LLP, attorneys for Plaintiff Bionpharma Inc. ("Bionpharma") in this action. Unless otherwise indicated, all statements made herein are based upon information and belief.

2. I submit this Declaration in support of Bionpharma's application by Order to Show Cause seeking (a) an injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure that requires defendant CoreRx, Inc. ("CoreRx") to continue to supply Bionpharma with its

requirements of enalapril maleate oral solution (the "Product") for the duration of the Master Manufacturing Supply Agreement (the "Agreement") under the terms thereof, or at least until Bionpharma can transfer manufacturing to, and obtain inventory from, a new facility subject to compliance with FDA regulations for pharmaceutical manufacturing; and (b) in order to prevent immediate and irreparable injury to Plaintiff as alleged in the Complaint as well as accompanying Declarations and Memorandum of Law, an order temporarily restraining and enjoining CoreRx, including all persons and entities acting in concert with it, from taking any action that would prevent it from performing under the Agreement if the Court were to grant the preliminary injunction.

3. Bionpharma is proceeding via an Order to Show Cause in order to obtain a decision on its motion seeking a preliminary injunction as a matter of exigency, and, hopefully, by no later than December 17, 2021. The exigency here is that this case involves CoreRx's willful and knowing breach of a contract that will result in irreparable damage to the goodwill and reputation that Bionpharma has built in the generic drug market, and will remove from the market the only existing cost-effective generic version of a drug used to treat severe cardiac disease, mostly in children.

4. The Complaint filed in this action, along with the Motion for a Preliminary Injunction and the supporting Declarations of Venkat Krishnan and Iltifat Hasan, provide the details regarding the Agreement that the parties entered into in November 2020 wherein CoreRx agreed to supply Bionpharma's requirements of the Product (generic to the branded product Epaned sold by CoreRx's sister company Azurity Pharmaceuticals), and Bionpharma agreed to purchase its requirements of the Product from CoreRx.[1] As noted therein, the purpose of the

[1] *See* Complaint, Exhibit A, Section 5.1 (copy of the Agreement, with financial terms and nonpublic information concerning the Product omitted).

Agreement is for Bionpharma to acquire Product for resale to its customers in the wholesale market for generic pharmaceuticals.

5. The urgency of this matter is predicated on CoreRx's willful and knowing breach of the Agreement, its one-day notice to Bionpharma that it would no longer supply the Product that it agreed to do under the terms of the Agreement, and CoreRx's failure to supply Product that was ordered by Bionpharma in August 2021 for delivery later this month, amongst other reasons.

6. Specifically, CoreRx has manufactured and Bionpharma has taken possession of approximately [redacted] of Product delivered pursuant to a purchase order submitted on August 26, 2021. Another approximately [redacted] of Product remain outstanding under this August 26 order. These bottles of Product had been scheduled to be shipped by CoreRx to Bionpharma by December 28, 2021. CoreRx refuses to supply the remainder of the Product ordered in August, and has refused to acknowledge a separate purchase order that Bionpharma submitted on December 3, 2021.

6. The failure to fulfill purchase orders duly submitted by Bionpharma in accordance with the terms of the Agreement means that Bionpharma will be unable to supply the Product to its customers. Bionpharma is facing irreparable and catastrophic loss of goodwill in the industry. Bionpharma spent years preparing to launch the Product, which gave it inroads to new customers and boosted its reputation and business. The sudden loss of the Product due to CoreRx's wrongful breach paints Bionpharma as an unreliable partner and distributor to be avoided.

7. As further explained in the accompanying Declaration of Bionpharma's founder, President and Chief Executive Officer Venkat Krishnan, given that CoreRx gave Bionpharma only one day's notice that CoreRx would not continue to supply Product under the Agreement, Bionpharma cannot secure an alternate supplier of Product before it exhausts the inventory of

Product it has on hand. Mr. Krishnan explains the cost that Bionpharma will need to expend (hundreds of thousands of dollars) and the time it will take (as long as nine months) to identify and bring online an alternate source of Product.[2] But even if things move faster than expected, Bionpharma will run out of Product and be unable to fill orders if CoreRx does not continue to supply in the interim. If this occurs, Bionpharma will suffer irreparable injury.

8. In addition, CoreRx's breach and refusal to supply Product, if not enjoined, will result in the removal from the market of the sole generic option for an otherwise cost-prohibitive drug used to treat severe cardiac disease, mostly in children. The loss of this generic drug from the market would be devastating to patients and families. The desperate public need for generic competition for the non-generic brand of this drug (Epaned) has been prominently featured in the news media, including the Washington Post, which noted that Epaned falls into a category of drugs where the brand creates a liquid formulation of an old drug and charges exorbitant prices for the reformulated drug, posing an incredible financial burden to families. Shefali Luthra, *The dilemma of kid-friendly pharmaceuticals: Safety comes at a steep price*, WASHINGTON POST (Apr. 21, 2017).

8. A true and correct copy of excerpts from the transcript of a November 10, 2021 hearing in *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-1286-LPS (D. Del.) is attached hereto as **Exhibit P**.

WHEREFORE, it is respectfully requested that Bionpharma's application be granted in its entirety.

[2] Krishnan Decl. ¶ 34.

Pursuant to 28 U.S.C. §1746 I hereby declare under penalty of perjury that the foregoing is true and correct.

DATED: December 13, 2021

By:_____

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